

REMARKS

Claims 1-9, 11-15, 17, 18, 20-48, 50, 52-73 and 75-80 are now pending in the application. The Examiner is respectfully requested to reconsider and withdraw the rejections in view of the amendments and remarks contained herein.

CLAIM OBJECTIONS

Claim 80 has been objected to for failing to clearly provide further structural limitation to the claims from which it depends. Applicants have amended claim 80 in order to clarify that the tracking elements are structurally different such that the tracking elements are uniquely identifiable. Applicants respectfully request that the Examiner withdraw his objection to this claim.

NEW CLAIMS

Applicants have added claims 81 – 93 to further define the invention. Support for these claims can be found in the Application as filed, for example, at paragraphs [0068] – [0070] and [0086]. Each of these new claims ultimately depends upon and includes the limitations of one of the independent claims. Applicants submit that these claims are also patentable over the cited reference for the reasons set forth below. Furthermore, each of the new claims contains further limitations that are not disclosed in the prior art, e.g., real-time tracking of tracking elements, tracking with six degrees of freedom and locking the member in a selected position and a selected orientation.

REJECTION UNDER 35 U.S.C. § 103

Claims 1-9, 11-15, 17-18, 22-30, 33-44, 47-48, 50, 52-73 and 77-80 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley et al. (U.S. Pat. No. 6,226,548; hereinafter "Foley") in view of Ellis (U.S. Pat. Pub. No. 2003/0011624; hereinafter "Ellis"). Claims 20-21, 31-32, 45-46 and 75-76 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Foley in view of Ellis, as applied to Claims 1, 22, 33 and 67, and further in view of Acker et al. (U.S. Pat. No. 6,332,089; hereinafter "Acker"). These rejections are respectfully traversed.

Applicants respectfully submit that none of the cited references, whether considered alone or in combination with each other, teaches the tracking of a localization element or tracking element attached to an implant member in order to provide a dynamic reference frame for the member as provided for by all of the claims.

The Examiner asserts that, for each of the independent claims, the Foley reference teaches all of the elements except for an imageless procedure, for which the Examiner relies upon Ellis (See, e.g., Office Action at pages 6-7). Applicants respectfully disagree.

The Examiner is correct that the Foley reference teaches only an image-based procedure (See, e.g., Office Action at pages 6-7). In Foley, an image is taken of a patient anatomy to which a fiducial array has been attached (See Foley at column 8, lines 9-26). This image is then loaded into surgical navigation system processor (Id.). The patient is then moved into the operating room and the patient anatomy is then registered to match the stored image, which may require image or anatomy manipulation (See Foley at column 8, lines 9-26 and column 9, line 64 to column 10,

lines 2). An implant, or portion thereof, is then navigated based on the position of the patient anatomy as registered with respect to the stored image (Id.).

In contrast to Foley above, the claims provide for a system and method in which the position of a patient anatomy may be dynamically tracked by tracking elements attached to portions of the implant attached to the patient anatomy. The tracking elements act as dynamic reference frames for the patient anatomy to which they are attached. In this manner, the position of each portion of the implant may be determined in real-time such that the relative movement of each portion of the implant (and the anatomy or member to which they are attached) may be determined during the procedure.

Each of independent claims 1, 22, 33, 53 and 67 provide for a system or method in which the position of a member to which a tracking element is attached may be tracked, e.g., by a processor, in order to provide a dynamic reference frame. In this manner, the "true" position of the member may be known in real-time and used throughout the procedure to assist in the final placement of the implant (See Application at paragraphs [0088] and [0116]).

Referring now to claim 1, Applicants respectfully submit that Foley does not disclose "a system for use in navigating an implantation of a selected construct" in which "said processor is operable to track said first localization element fixed to said first member and said second localization element fixed to said second member such that said first and second localization elements act as dynamic reference frames for said first and second members" as provided.

Referring now to claim 22, Applicants respectfully submit that Foley does not disclose "a system for use in determining a position of a first implantable member and planning and navigating relative to the first member for positioning a second member to interact with said first member" in which "said processor is operable to track the tracking element fixed to said first member such that the tracking element acts as a dynamic reference frame for said first member" as provided.

Referring now to claim 33, Applicants respectfully submit that Foley does not disclose "a method of implanting a construct having at least a first member, a second member, or a third member" comprising "tracking the first tracking element connected to the first member and the second tracking element connected to the second member such that the first and second tracking elements act as dynamic reference frames for the first and second members" as provided.

Referring now to claim 53, Applicants respectfully submit that Foley does not disclose "a method of implanting a construct of at least a first member, a second member, or a third member substantially at least one of percutaneously or minimally invasively" comprising "tracking the position of the first member or the second member in order to provide a dynamic reference frame" as provided.

Referring now to claim 67, Applicants respectfully submit that Foley does not disclose "a system for use in determining a position of a first implantable member and planning and navigating relative to the first member for positioning a second member to interact with said first member" in which "said processor is operable to track said tracking element attached to the first member such that said tracking element acts as dynamic reference frames for the first member" as provided.

Even if Foley were combined with Ellis, the combination would not teach the invention as provided for by the claims above. The Examiner relies upon the Ellis reference solely for its alleged teaching of an “imageless” procedure (See, e.g., Office Action at pages 6-7). Applying the teachings of Foley in an “imageless” procedure, even if possible, would not provide the use of a “dynamic reference frame” as claimed. Neither Foley nor Ellis, whether considered alone or in combination with each other, teaches the tracking of a localization element or tracking element attached to an implant member in order to provide a dynamic reference frame for the member as provided by all of the claims.

Essentially, the Foley reference is directed to a system and method in which position information of a portion of an implant is determined by a pre-operative scan and, then, by a registration of the position during the procedure (See Foley at column 9, line 44 to column 10, line 2). Another portion of the implant is then guided to the position of the portion of the implant, as saved by the registration process, by use of the navigation system (See Id. at column 10, line 62 to column 11, line 3). The present claims, in contrast, relate to a system and method in which each portion of the implant is tracked by the navigation system at the same time such that at least a portion of the implant can provide a dynamic reference frame for the other portion(s) of the implant (See claims 1, 22, 33, 53 and 67 above). Neither Foley nor Ellis teach this aspect of the claims.

Applicants therefore respectfully submit that independent claims 1, 22, 33, 53 and 67 are patentable over the cited references. As claims 2-9, 11-15, 17-18, 23-30, 34-44, 47-48, 50, 52, 54-66, 68-73 and 77-80 depend upon and include the limitations

of one of the independent claims, Applicants submit that these claims are also patentable over the cited reference for the same reasons. Applicants request that the rejections under Section 103(a) be withdrawn.

CONCLUSION

It is believed that all of the stated grounds of rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider and withdraw all presently outstanding rejections. It is believed that a full and complete response has been made to the outstanding Office Action and the present application is in condition for allowance. Thus, prompt and favorable consideration of this amendment is respectfully requested. If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (248) 641-1600.

Respectfully submitted,

Dated: Dec. 29, 2008

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